

PD4 Exh 14

McKesson Operations Manual

for Pharma Distribution

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Lifestyle Drug Monitoring Program

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General Description

Task: This procedure outlines requirements and activities to proactively review customer's purchases of DEA identified "Lifestyle Drugs" and actions to take based upon analysis of customer purchases.

Purpose: McKesson has been proactively working with the DEA to enhance current practices for the monitoring and review of suspicious orders. Trends in the marketplace require McKesson to reevaluate the methodology utilized to review customer orders and their business models.

The DEA expects the supplier to "*know their customer*". This means understanding the customer's business, *why* they purchase as well as how much they purchase. Factors such as type of business, internet activities, type and quantity of products purchased should be considered when evaluating a customer.

Reports

Two Business Objects reports, Daily Dosage Summary Report and Dosage Limit Tracking Detail, have been developed to allow McKesson to monitor customer purchases of controlled substances by the net number of dosage units sold based on the DEA's Controlled Substance Generic Base Code ID. McKesson will investigate customer activity when sales of a given generic base ingredient exceed a predefined dosage unit threshold within a calendar month. Initially all items will be investigated at the same threshold level, however the level may be changed per item at Regulatory Affairs discretion. The same dosage threshold will be used for all classes of customers.

This reporting process is targeting controlled substances that the DEA considers "lifestyle" drugs. These drugs are highly abused and are commonly found in illegal internet pharmacies.

Currently, the controlled substances being monitored by these reports are:

Generic ingredient	Base code	Dosage Threshold
Oxycodone	9143	8,000
Hydrocodone	9193	8,000
Alprazalam	2882	8,000
Phentermine	1640	8,000

Additions or deletions of items will be managed through the Regulatory Department by submitting a problem request to Business Intelligence- Functional (BI-FUNC).

For the purpose of these reports, all sales to a DEA license number are being accumulated, therefore sales to multiple account numbers with the same DEA license number are consolidated. Sales are added together regardless of fill dc.

Daily Dosage Summary Report

This report will summarize customers who have purchased quantities of all products containing the identified base code in excess of the threshold for the item. For example all sales and credits of McKesson items containing Hydrocodone will be added together and reported if the total doses exceed 8,000 unit. The daily report will systematically be sent via email to the DCM and their designee, Sales Management, and Regulatory department. It will be the DCM's responsibility to review and act on the reports according to the processes listed below.

Review of Summary Report

The report will be generated as customers exceed the dosage unit threshold. Each customer appearing on the report must be evaluated to the legitimacy of their order quantity. Once an account appears on the report, it will continue to show up on the report until the end of the month. You should start your evaluation when the account appears on the report; do not wait until the end of the month to start the process.

If the account is a large customer that McKesson expects to purchase in large quantities, for example: institutional, warehouse accounts, government, or mail order, then you will generally only have to perform a Level I review. However, large spikes of any customer including hospitals, warehouse accounts, or government accounts must be evaluated.

Generic Dosage Limit Tracking Detail Report

This is an on demand report that allows a DC to research a customer that has been reported on the Summary Report. Once a customer has been identified from the summary report, this report will provide detail of all sales and credits during any given time frame.

The user logs into Business Objects, runs the report and enters the DEA numbers and dates of interest.

Manually Running Reports

Both reports can be run manually within Business Objects, they are located in the Corporate Documents folder.

Since the reports may run a long time, the user should run these reports using the Business Objects PC client rather than through the Business Objects web interface. Using the web interface, the reports may time out before completion.

Download and install the "Business Objects Full Client Reporter" following the instructions found on the Business Objects home page at [**Business Objects**](#).

Access to Business Objects is granted by making a standard request to IT Security. Complete an OnLine Access Request at [**On Line Security Request Form**](#).

Problems with installing or using Business Objects should be addressed by calling the McKesson Internal Help Desk at 888-HELPMCK.



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Overview of Detailed Steps

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Detailed Steps

1. Level I Review

1.1 If the customer appears on a previous month's report for the same item

Evaluate the customer's purchases relative to the past three month's purchases. The evaluation should include but not necessarily be limited to the following criteria:

- ◆ Previous sales were validated and approved.
- ◆ Sales have not increased more than 25% from any previous month.
- ◆ Sales are not increasing steadily.
- ◆ Sales are consistent with the customer type.
- ◆ Sales are consistent with any previous Sales or Customer communication.

Document findings on the LDMP Tracking Spreadsheet.

1.2 Determine if the sales are approved or inconclusive

If the evaluation indicates that the customer's purchases are reasonable and that no further investigation is required, proceed to the LDMP Approval and Sign Off Step. If the evaluation is inconclusive continue to the next step to gather and analyze further information.

1.3 If this is the first time the item has been listed for the customer or further investigation is indicated

Proceed with the following evaluation steps until sales are determined to be reasonable for the customer.

- ◆ Generate and review the Dosage Limit Detail Report for the customer for the previous 6 months. Use this to review the last 6 months sales for any trends.
- ◆ Review daily DU45 Suspicious Orders Report for entries for this customer. Has the customer appeared previously? Have we reported their sales to the DEA via the DU45?
- ◆ Review Customer Purchasing Profile if one has been completed; are sales consistent with their profile?
- ◆ Perform a web search on the customer to review possible business practices
- ◆ Contact the appropriate Sales representative to determine reasoning behind the sales.
- ◆ Contact the customer to inquire on sales volume, expected volume and nature of business.

Document findings on the LDMP Tracking Spreadsheet.

1.4 Determine if the sales are approved or inconclusive

If the evaluation indicates that the customer's purchases are reasonable and that no further investigation is required, proceed to the LDMP Approval and Sign Off Step.

If the evaluation is not conclusive:

- ◆ Begin cutting order quantities on identified items
- ◆ Escalate to the Level II Review



2. Level II Review

2.1 Notify management that a Level II Review has been initiated

Email the VPDO and the Director or VP of Regulatory Affairs to notify them that a Level II Review has been started.

2.2 Conduct a customer site examination

Visit the customer's site with the intent to observe their location and clientele. Observations should include items such as the following:

- ◆ Customer Traffic - does the customer volume seem in line with their business type?
- ◆ Signage - does the customer advertise themselves to the public in a manner consistent with their business type?
- ◆ Location - is the customer's business in a site that appears consistent with their business type and volume? For example, consider the area's population and surrounding businesses.
- ◆ Store Size - does the customer's square footage appear to be appropriate for their business type and volume?

Document findings on the LDMP Tracking Spreadsheet.

2.3 Conduct an interview with the customer

If evidence is not conclusive at this point, the customer must be contacted and an interview conducted with them regarding their purchases. This meeting should be conducted with representation from both Sales and Operations.

At the conclusion of the interview, the customer signs the Customer Declaration of Controlled Substance Purchases attesting to their business practices. After the interview, the McKesson representative will complete and sign off on the LDMP Questionnaire; this questionnaire will summarize the customer's responses.

Important: The customer is not allowed to complete the questionnaire themselves, the questionnaire is meant to document interactive communications between McKesson and the customer.

Instructions for performing the interview

1. Notify the appropriate Sales team member that an interview must be conducted with the customer.
2. Sales or Operations should contact the customer and request a meeting at a mutually agreed upon date and time.
 - ◆ Schedule the meeting for as soon as is possible for all parties; the DEA expects McKesson's responses to suspicious activities to be prompt and timely.
 - ◆ Ensure that the customer understands that McKesson is performing due diligence activities for the benefit of both McKesson and the customer.
3. Print and review the LDMP Questionnaire and Customer Declaration of Controlled Substance Purchases prior to visiting the customer.
4. Conduct the interview.
5. Have the customer sign the declaration.
6. Thank the customer and exit the interview
7. Complete and sign the LDMP Questionnaire based upon responses provided by the customer.

Document findings on the LDMP Tracking Spreadsheet.

2.4 Determine if the sales are approved or inconclusive

If the evaluation indicates that the customer's purchases are reasonable and that no further investigation is required, proceed to the LDMP Approval and Sign Off Step.

If the evaluation is not conclusive, escalate to the Level III Review.



3. Level III Review

3.1 Contact Home Office

If Level I and Level II reviews have not been conclusive, Distribution and Sales should contact the Director or Vice President of Regulatory Affairs to discuss finding and determine next steps. The Regional SVP should be notified at this time regarding the escalation of review.

3.2 Contact the local DEA office

The local DEA office should be contacted to determine if the account is in good standing with the agency; this will be done by DC Management or Regulatory Affairs. Findings must be shared between DC Management and Regulatory Affairs.

3.3 Senior Management Review of Findings

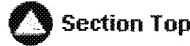
Regulatory Affairs will schedule and conduct meetings with the Law Department and Senior Management to present the findings of the review process and discuss next steps.

3.4 Contact DEA Headquarters

With the Law Department's guidance, Regulatory Affairs or Counsel will contact the DEA Headquarters to discuss our findings.

3.5 Final determination if the sales are approved or inconclusive

The final review of customer purchases and decisions regarding their purchases will be determined by the Law Department and Senior Vice President.



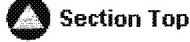
4. Actions if sales are not approved

4.1 DEA Notification

Regulatory Affairs will notify the DEA Headquarters and Local Office of McKesson's findings and any decisions regarding continued business with the customer.

4.2 Customer Notification

If there are outcomes to the review that impact the customer relationship with McKesson, Sales or Distribution Management will notify the customer.



5. LDMP Approval & Sign Off Process

When a review of a customer's purchases is conducted, the attached form will be utilized to document findings and McKesson Management sign off.

Required Sign Offs:

Level I Review:
DC Manager

Level II Review:
DC Manager, Sales Manager, Vice President of Operations (VPDO), Director or Vice President of Regulatory Affairs

Level III Review:
DC Manager, Sales Manager, Vice President of Operations (VPDO), Regional SVP, Director or Vice President of Regulatory Affairs, SVP of Operations

6. Record Retention Methology

Records will be maintained centrally by Regulatory Affairs although it is recommended that the DC maintain a copy for their own records as well. Reports will be emailed to Regulatory Affairs monthly or on an "as completed" basis depending on the document.

Daily Dosage Tracking Reporting:

The distribution centers and Regulatory Affairs will maintain copies of the report generated on the last business day of the month for at least two years. The DC does not need to send a copy to Regulatory Affairs, they receive their own copy automatically.

LDMP Tracking Spreadsheet:

This report should be completed and sent to Regulatory Affairs by the 10th of the month for the previous month's data. Copies should be maintained for at least two years.

Email the report to Jan Phillips at jan.phillips@mckesson.com - in the subject include the following: "LDMP Tracking Report for DC xxx for month year".

Example: **LDMP Tracking Report for DC 109 for May 2007**

Investigation Documentation:

As each investigation is completed all the related documents should be attached into a single email to send to Regulatory Affairs. The number and type of supporting documents will depend on how in depth a review was necessary. The Daily Dosage Summary Report **is not needed** in the review's documentation because the DC and Regulatory Affairs will be maintaining the last report for the month.

Email the documentation to Jan Phillips at jan.phillips@mckesson.com - in the subject include the following text "customer DEA# YYYYMM Level x Review"

Example: **PM0022929 200705 Level II Review**



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Attachments

LDMP Tracking Log

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LDMP Customer Questionnaire

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LDMP Review McKesson Sign Off

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LDMP Customer Declaration of Controlled Substance Purchases

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